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(54) **SELF-DILATING CANNULA**

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(51) **Int. Cl.**

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A61M 25/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 1/3653*** (2013.01); ***A61M 29/00*** (2013.01); *A61M 25/005* (2013.01); *A61M 25/007* (2013.01); *A61M 25/0041* (2013.01); *A61M 2025/0063* (2013.01)

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CPC A61M 1/3653; A61M 29/00; A61M 2025/0063; A61M 25/005; A61M 25/007

USPC 604/164.01, 164.02, 164.09–164.11, 604/164.13

See application file for complete search history.

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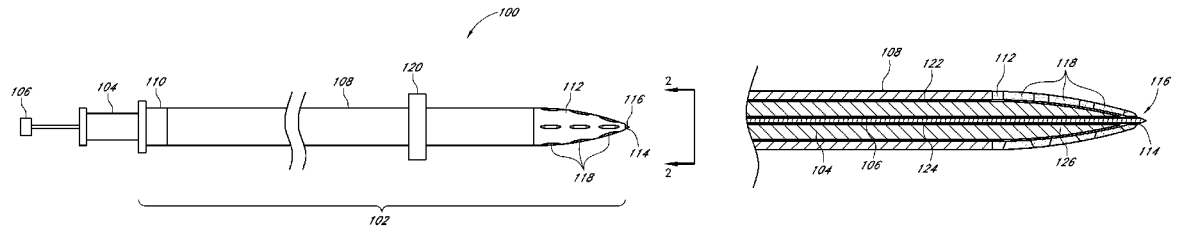
(57) **ABSTRACT**

A self-dilating cannula for introduction into a patient's vasculature includes an elongate body and an atraumatic tip. The elongate body has a proximal end, a distal end, and a fluid-flow lumen extending therebetween. The atraumatic tip is positioned at the elongate body's distal end and has a blunted end and a conical shape. The atraumatic tip includes a plurality of fluid-flow openings proximal to the blunted nose that are configured to disperse fluid from the fluid-flow lumen in a plurality of directions with respect to the atraumatic tip. The atraumatic tip also includes an opening in the blunted nose that is sized to a guidewire.

17 Claims, 3 Drawing Sheets



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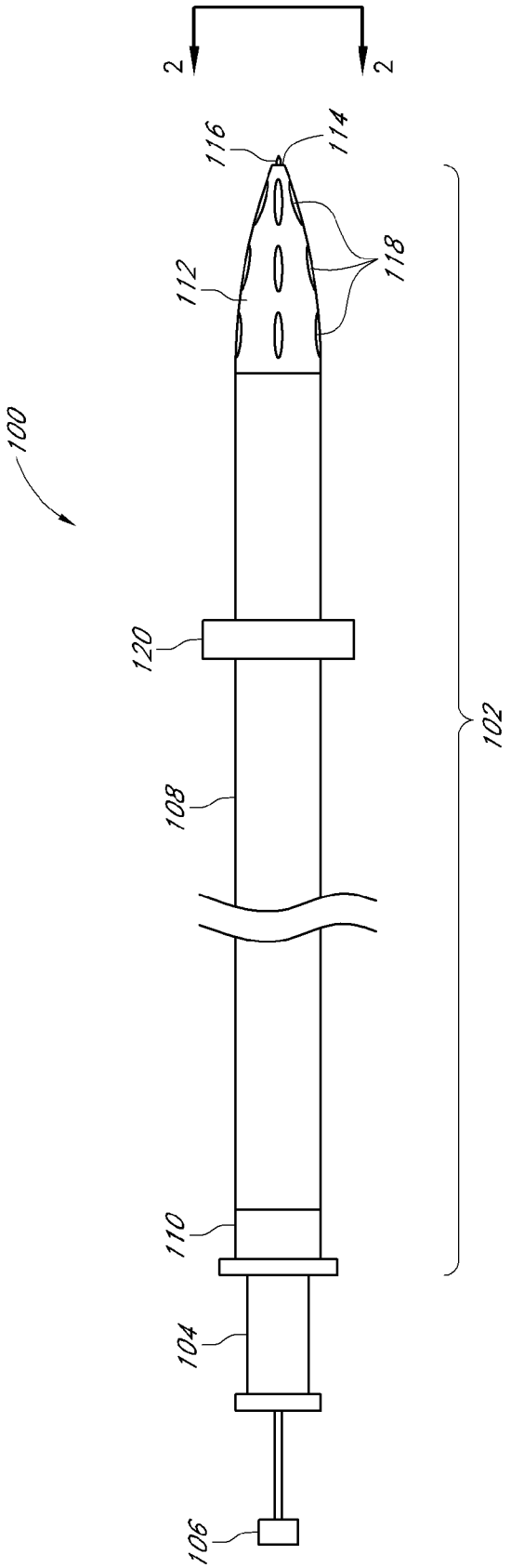

FIG. 1

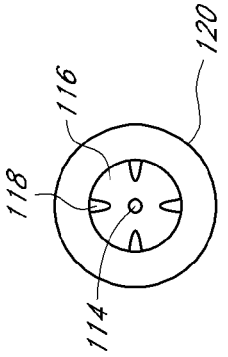

FIG. 2

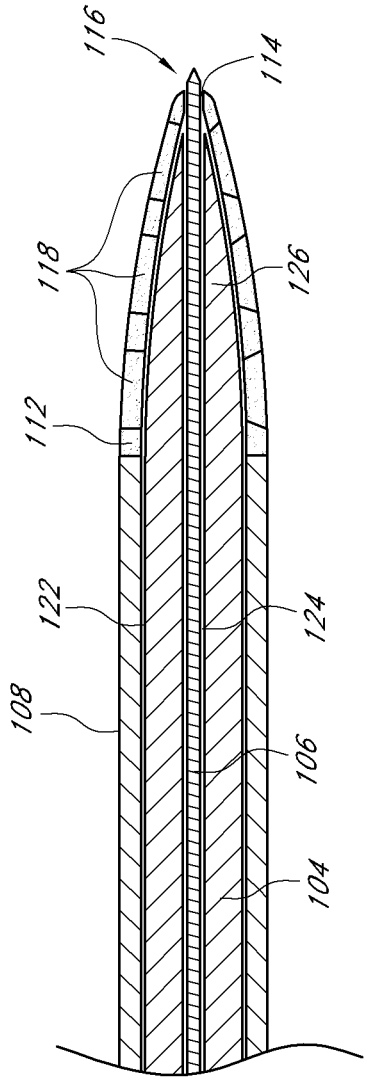

FIG. 3

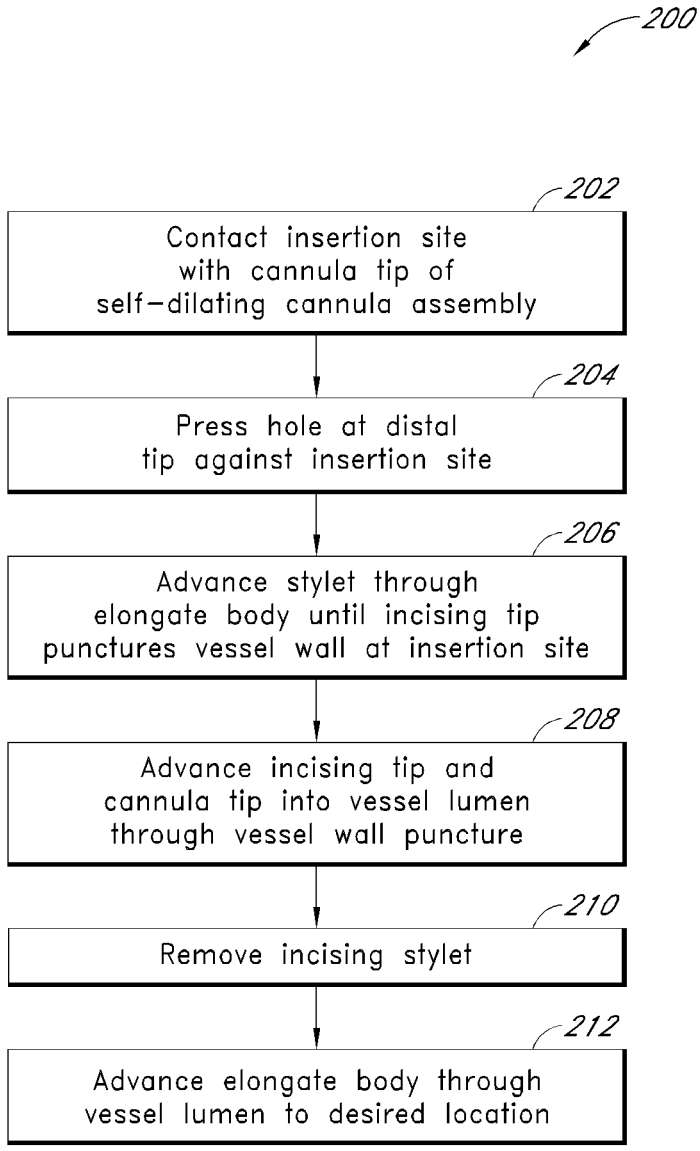
200
202
Contact insertion site with cannula tip of self-dilating cannula assembly
204
Press hole at distal tip against insertion site
206
Advance stylet through elongate body until incising tip punctures vessel wall at insertion site
208
Advance incising tip and cannula tip into vessel lumen through vessel wall puncture
210
Remove incising stylet
212
Advance elongate body through vessel lumen to desired location

FIG. 4

SELF-DILATING CANNULA

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 61/288,752, filed Dec. 21, 2009, the entirety of which is hereby incorporated by reference. This application is also related to U.S. Provisional Application Nos. 61/288,614 and 61/288,763, which are incorporated by reference in their entireties, herein.

SUMMARY

In one embodiment, a self-dilating cannula is configured for arterial perfusion or venous drainage. The cannula includes a conical tip that has a blunted nose, which provides self-dilation and minimizes the incision required for cannula introduction into a patient's vasculature. The canula's tip includes multiple ports that are configured to disperse fluid flow at a lower velocity in multiple directions. The cannula's tip also includes a small hole configured to be relatively conforming to a guidewire. The cannula is configured to receive the guidewire as the cannula is advanced through the patient's vasculature over the guidewire.

The cannula body includes an obturator, which can extend through the cannula's tip, or terminate within the cannula's body. The obturator includes a central lumen configured to receive a stylet. The stylet allows the cannula and obturator to be pre-shaped, or given a predetermined shape, which provides simplified remote insertion. The stylet also provides additional column strength to the cannula-obturator assembly. The stylet can include a sharpened incising distal tip to facilitate insertion of the cannula assembly into the patient's vasculature.

The cannula body can be thick- or thin-walled. In a thin wall configuration, the cannula body can include a reinforcing element to provide additional column strength. For example, in one embodiment, the cannula body includes a wound wire, spring, or discrete sections of material that are stiffer than the overlying cannula material.

In one embodiment, the cannula also includes an external concentric stop which limits the distance the tip of the cannula can be inserted in the patient's vasculature. The cannula may be used in a variety of applications, and at a variety of insertion sites, including the aorta, axillary vessels, femoral vessels, superior vena cava, and/or right atrium of the patient's heart.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a side view of a self-dilating cannula assembly, in accordance with one embodiment;

FIG. **2** illustrates a distal end view observed along line **2-2** of the cannula assembly of FIG. **1**;

FIG. **3** illustrates a partial cross-sectional view of the cannula assembly of FIG. **1**; and

FIG. **4** illustrates a flow chart of one embodiment of a method of inserting a cannula into a bodily lumen.

DETAILED DESCRIPTION

FIG. **1** illustrates one embodiment of a self-dilating cannula assembly **100**. The cannula assembly **100** includes a cannula **102**, obturator **104**, and stylet **106**. The cannula **102** includes a tubular, elongate body **108** that terminates at a connector **110** at the elongate body's proximal end and at a cannula tip **112** at the elongate body's distal end. An opening **114** located at the tip's distal end is sized to receive a piercing tip **116** of the stylet **106**. The cannula tip **112** includes ports **118** configured to permit adequate fluid flow through the cannula **102** and to, or from, a patient's vasculature. An optional stop **120** allows a clinician to control the degree of insertion of the distal end of the cannula **102** into a patient's vasculature. The stop **120** is slideable along the elongate body **108**, but is held in position with a locking mechanism. In one embodiment, the locking mechanism includes a friction grip between the stop **120** and the elongate body **108**.

The cannula tip **112** can have a conical shape and/or a blunted and/or rounded nose. The taper and curvature of the tip **112** is selected to provide self-dilation of an opening at an insertion site as the cannula **102** is advanced through the opening. The cannula tip's shape also minimizes the incision required to insert the cannula **102** into the patient's vasculature. In one embodiment, the diameter of the distal end of the cannula tip **112** is about 0.04", 0.06", or 0.10".

The ports **118** are configured to disperse fluid flow at low velocity in multiple directions. For example, in one embodiment, ports **118** are longitudinally and/or circumferentially spaced along the tip's **112** wall. The opening **114** at the cannula tip's distal end is configured to conform to a guidewire and/or stylet.

In one embodiment, the obturator **104** extends through the elongate body **108** and into the cannula tip **112**. In another embodiment, the obturator **104** extends only through the elongate body **108** and terminates within it. The obturator **104** is designed to accept a sytlet **106**. The stylet **106** may be used to shape and/or apply a predetermined curvature to the cannula **102** prior to insertion into the patient's vasculature. In some cases, shaping the cannula **102** by bending the stylet **106** simplifies the procedure of inserting the cannula **102** into the patient's vasculature. Furthermore, the stylet **106** also provides additional column strength to the cannula **102**, which further simplifies insertion. In one embodiment, the stylet **106** has an outer diameter of about 0.038".

The tissue-piercing tip **116** of the stylet **106** greatly simplifies the cannula-insertion process by acting as a leading-edge cutter. For example, the self-dilating cannula system **100** allows a clinician to position the cannula **102** with respect to a tissue insertion site, and with a single motion, pierce the tissue wall at the insertion site, insert and advance the cannula **102** into the patient's vasculature. The clinician may avoid the time-consuming procedures of incising the tissue wall at an insertion site, clamping the incision to stop blood flow, and utilizing a separate set of dilators to expand the incision at the insertion site, as well as the vessel lumen, in order to accept a cannula. Instead, the self-dilating cannula system **100** may be introduced into the patient's vasculature quickly, safely, and under direct vision.

The elongate body **108** can include a thick- or thin-wall configuration. For example, the elongate body **108** can have a wall thickness in the range of about 0.020"-0.080", 0.040"-0.060", or about 0.050". The elongate body **108** wall can optionally include a reinforcing element (not shown). For example, in some embodiments, the elongate body **108** wall includes a wire, a wound wire, a spring, or areas or sections of material having increased stiffness compared to other areas or sections of materials.

FIG. **2** illustrates the distal end view of the cannula assembly **100** observed along line **2-2** of FIG. **1**. Several ports **118** located on the cannula tip **112** are sized and oriented to allow blood to smoothly flow along the direction of a longitudinal axis of the elongate body **108**. Such ports **118** allow fluid to

flow through and exit (or enter) the cannula **102** via ports **118** in the cannula tip **112** that open along the elongate body's longitudinal axis.

FIG. **3** illustrates a partial cross-sectional view of the cannula assembly **100** of FIG. **1**. The cannula's elongate body **108** includes an elongate body lumen **112**, which is sized to receive the obturator **104**. The elongate body lumen **122** diameter is slightly larger than the outside diameter of the obturator **104** so that the obturator can freely slide in and out of elongate body **108**, as desired. The obturator **104** includes an obturator lumen **124**, which is sized to receive the stylet **106**. Similarly, the obturator lumen **124** diameter is slightly larger than the outside diameter of the stylet **106** so that the stylet can freely slide in and out of the obturator, as desired.

The degree or amount of obturator **104** insertion into the elongate body **108** may be controlled by an interference between the distal end **126** of the obturator **104** and the inside surface of the cannula tip **112**. In another embodiment, the amount of obturator **104** insertion into the elongate body **108** is controlled by a limit (not shown) positioned near the proximal end of the obturator **104**. The limit is designed to interfere with (e.g., contact) the connector **110** located at the elongate body's **108** proximal end.

Similarly, the degree or amount of stylet **106** insertion into the obturator **104** may be controlled by an interference between the distal end of the stylet **106** and the inside surface of the obturator's **104** distal end. In another embodiment, the amount of stylet **106** insertion into the obturator **104** is controlled by a limit (not shown) positioned near the proximal end of the stylet. The limit is designed to interfere with (e.g., contact) an end portion located at the obturator's **104** proximal end.

FIG. **4** illustrates a method **200** of inserting a cannula into a bodily lumen of a medical patient. The cannula utilized to perform the method **200** can be any of the cannulae described above, including, but not limited to the cannula assembly **100** of FIGS. **1-3**. In other embodiments, a different cannula is utilized.

The method **200** begins at block **202**, where an insertion site is contacted with a cannula tip of a self-dilating cannula. At block **204**, a hole located at the distal end of the distal tip is pressed against the insertion site. An obturator may be inserted into the cannula to provide column strength and additional stiffness and control over the cannula. At block **206**, a stylet is advanced through the elongate body of the cannula until the stylet's incising tip exits the cannula hole and punctures the tissue at the insertion site. The tissue can include one or more of skin, muscle, fat, and a vessel wall, such as a blood vessel, artery, vein, or other bodily conduit. The incising tip of the stylet punctures the tissue at the insertion site while the distal end of the cannula tip is held in contact with the vessel wall around the insertion site.

At bock **208**, the incising tip and cannula tip are initially advanced into the vessel lumen through the vessel wall puncture. The incising stylet is removed from the patient's vasculature and the obturator lumen at block **210**. The incising stylet is removed to reduce the risk of undesired damage to the luminal wall of the patient's vessel. At block **212**, the elongate body is further advanced through the vessel lumen. If a stop is provided, the cannula is advanced until the stop contacts tissue around the insertion site.

In one embodiment, the cannula is inserted into the patient's vasculature over a guidewire. For example, after the incising stylet is removed, a guidewire is inserted through the obturator lumen in which the stylet had been inserted prior to removal. The guidewire is advanced through the obturator lumen until it exits the hole at the cannula's distal tip, and then enters the patient's vasculature through the puncture at the insertion site. The cannula slides over the guidewire and follows the guidewire through the patient's vasculature as it is advanced.

The self-dilating cannula system can be used in any of a variety of clinical applications. For example, the cannula system can be inserted into any blood-carrying vessel, chamber, or volume within a patient, including, but not limited to, the aortic artery, the axillary artery, the femoral artery, the subclavian artery, the inferior vena cava, the superior vena cava, and/or a chamber of the heart, including the right or left atrium or the right or left ventricle.

The self-dilating cannula can be used for arterial perfusion and/or venous drainage. For example, once introduced into a patient's aortic artery (as described above), the stylet and obturator are removed from the cannula. The connector at the cannula's proximal end may then be connected to the output port of a cardio-pulmonary bypass pump, such that externally oxygenated blood from the cardio-pulmonary bypass pump is introduced into the patient's aorta via the cannula. The self-dilating cannula can be guided percutaneously to the appropriate position within the person's aorta by using a guidewire. Alternatively, the self-dilating cannula can be directly inserted into the patient's aorta by least-invasive, port, or open chest surgical techniques.

In another embodiment, the self-dilating cannula is used to retrieve deoxygenated blood from the patient's vasculature. For example, the self-dilating cannula may be advanced percutaneously through the patient's femoral artery, to the inferior or superior vena cava. The connector at the cannula's proximal end may then be connect to the input port of a cardio-pulmonary bypass pump, such that deoxygenated blood retrieved from the patient is externally reoxygenated and then reintroduced into the patient's vasculature. In one embodiment, two self-dilating cannulae are provided. For example, a first cannula is coupled between the patient's venous system (e.g., superior and/or inferior vena cava) and a cardio-pulmonary bypass pump, and a second cannula is coupled between the cardio-pulmonary bypass pump and the patient's arterial system (e.g., aorta).

In certain embodiments, features of the cannulae and related methods described above are applied to, or use in accordance with any one or more of the devices and methods described in U.S. Pat. Nos. 6,837,864 and 6,902,545, which are incorporated by reference in their entireties herein.

What is claimed is:

1. A self-dilating cannula assembly for introduction into a patient's vasculature, comprising:

a stylet comprising a distal end;

a cannula, comprising:

an elongate body, the elongate body having a proximal end, a distal end, and a fluid-flow lumen extending therebetween, wherein the fluid-flow lumen is the only longitudinally-extending lumen defined in the cannula; and

an atraumatic tip positioned at the elongate body's distal end, the atraumatic tip having a blunted nose and a conical shape, wherein the atraumatic tip comprises a plurality of axially elongate fluid-flow openings on a conical portion of the atraumatic tip proximal to the blunted nose and configured to disperse fluid from the fluid-flow lumen in a plurality of directions with respect to the atraumatic tip, and wherein the atraumatic tip further comprises an opening in the blunted nose sized to a guidewire;

an external concentric stop slideable along the elongate body, the stop including a locking mechanism for hold-

ing the stop in place on the elongate body for controlling a degree of insertion of the distal end of the self-dilating cannula into a patient's vasculature; and

an obturator, comprising a lumen sized to receive the stylet, wherein the obturator is configured to reduce fluid flow through the fluid-flow lumen during introduction of the cannula into a blood vessel, the obturator sized to slide within the fluid-flow lumen from the proximal end towards the distal end of the fluid-flow lumen, wherein the obturator and stylet are sized to provide an interference fit between the distal end of the stylet and an inside surface of a distal end of the obturator, wherein the interference fit is configured to control an amount of stylet insertion into the obturator.

2. The self-dilating cannula assembly of claim **1**, wherein the distal end of the stylet comprises an incising end, wherein the opening of blunted nose is sized to the stylet.

3. The self-dilating cannula assembly of claim **2**, wherein the stylet is configured to provide a predetermined shape to the elongate body when inserted therein.

4. The self-dilating cannula assembly of claim **2**, wherein the stylet is configured to provide stiffness to facilitate insertion in a vessel lumen.

5. The self-dilating cannula assembly of claim **1**, further comprising a reinforcing element configured to provide increased stiffness to the elongate body.

6. The self-dilating cannula assembly of claim **5**, wherein the reinforcing element comprises a wire.

7. The self-dilating cannula assembly of claim **5**, wherein the reinforcing element comprises a spring.

8. A self-dilating cannula assembly for introduction into a patient's vasculature, comprising:

a stylet comprising an incising end;

a cannula, comprising:

an elongate body, the elongate body having a proximal end, a distal end, and a fluid-flow lumen extending therebetween, wherein the fluid-flow lumen is the only longitudinally-extending lumen defined in the cannula; and

an atraumatic tip positioned at the elongate body's distal end, the atraumatic tip having a blunted nose and a conical shape, wherein the atraumatic tip comprises a plurality of fluid-flow openings proximal to the blunted nose and configured to disperse fluid from the fluid-flow lumen in a plurality of directions with respect to the atraumatic tip, and wherein the atraumatic tip further comprises an opening in the blunted nose sized to a guidewire, wherein the atraumatic tip is configured to dilate an incision in a wall of a blood vessel when advanced therethough, wherein the incision is the size of the incising end of the stylet, and wherein the incising end of the stylet is capable of being inserted through the opening in the blunted nose;

an external stop disposed concentrically around the elongate body, wherein the stop is slideable along the elongate body and includes a locking mechanism for holding the stop in place on the elongate body for controlling a degree of insertion of the distal end of the self-dilating cannula into a patient's vasculature; and

an obturator, comprising a lumen sized to receive the stylet, wherein the obturator is configured to reduce fluid flow through the fluid-flow lumen during introduction of the cannula into a blood vessel, the obturator sized to slide within the fluid-flow lumen from the proximal end towards the distal end of the fluid-flow lumen, wherein the obturator and stylet are sized to provide an interference fit between the incising end of the stylet and an inside surface of a distal end of the obturator, wherein the interference fit is configured to control an amount of stylet insertion into the obturator.

9. The self-dilating cannula assembly of claim **8**, wherein the fluid-flow openings are on a conical portion of the atraumatic tip.

10. The self-dilating cannula assembly of claim **8**, wherein the fluid-flow openings are sized and oriented to allow blood to smoothly flow along a direction of a longitudinal axis of the elongate body.

11. The self-dilating cannula assembly of claim **8**, wherein the fluid-flow openings are aligned in a plurality of longitudinally spaced rows and are aligned in a plurality of circumferentially spaced columns on the atraumatic tip.

12. A self-dilating cannula assembly for introduction into a patient's vasculature, comprising:

a stylet comprising a distal end;

a cannula, comprising:

an elongate body, the elongate body having a proximal end, a distal end, and a fluid-flow lumen extending therebetween, wherein the fluid-flow lumen is the only longitudinally-extending lumen defined in the cannula; and

an atraumatic tip positioned at the elongate body's distal end, the atraumatic tip having a blunted nose and a conical shape, wherein the atraumatic tip comprises a plurality of axially elongate fluid-flow openings proximal to the blunted nose and configured to disperse fluid from the fluid-flow lumen in a plurality of directions with respect to the atraumatic tip, wherein the axially elongate fluid-flow openings are sized and oriented to allow blood to smoothly flow along a direction of a longitudinal axis of the elongate body, and wherein the atraumatic tip further comprises an opening in the blunted nose sized to a guidewire; and

an obturator, comprising a lumen sized to receive the stylet, wherein the obturator is configured to reduce fluid flow through the fluid-flow lumen during introduction of the cannula into a blood vessel, the obturator sized to slide within the fluid-flow lumen from the proximal end towards the distal end of the fluid-flow lumen, wherein the obturator and stylet are sized to provide an interference fit between the distal end of the stylet and an inside surface of a distal end of the obturator, wherein the interference fit is configured to control an amount of stylet insertion into the obturator.

13. The self-dilating cannula assembly of claim **12**, the distal end of the stylet comprising an incising end, wherein the opening of blunted nose is sized to the stylet, wherein the atraumatic tip is configured to dilate an incision having a diameter of the stylet.

14. The self-dilating cannula assembly of claim **13**, wherein the stylet has a diameter of about 0.038 inches and the atraumatic tip is configured to dilate an incision having a diameter of about 0.038 inches.

15. The self-dilating cannula assembly of claim **12**, wherein the axially elongate fluid-flow openings are both longitudinally and circumferentially spaced along the atraumatic tip.

16. The self-dilating cannula assembly of claim **12**, wherein the axially elongate fluid-flow openings are arranged in at least three longitudinally spaced rows on the atraumatic tip.

17. The self-dilating cannula assembly of claim 12, wherein the axially elongate fluid-flow openings are axially aligned in at least one column on the atraumatic tip.

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